PARAMETER COMPENSATED PULSE OXIMETER

REFERENCE TO RELATED APPLICATIONS

[0001]   The present application claims priority benefit under 35 U.S.C. §119(e) from U.S. Provisional Application No. 60/413,494, filed September 25, 2002, entitled "Parameter Compensated Pulse Oximeter," which is incorporated herein by reference.

BACKGROUND OF THE INVENTION

[0002]   Pulse oximetry is a noninvasive, easy to use, inexpensive procedure for measuring the oxygen saturation level of arterial blood. Pulse oximeters perform a spectral analysis of the pulsatile component of arterial blood in order to determine the relative concentration of oxygenated hemoglobin, the major oxygen carrying constituent of blood, and deoxygenated (depleted) hemoglobin. These instruments have gained rapid acceptance in a wide variety of medical applications, including surgical wards, intensive care units, general wards and home care by providing early detection of decreases in the arterial oxygen supply, which reduces the risk of accidental death and injury.

[0003]   FIG. 1 illustrates a pulse oximetry system 100 having a sensor 110 and a monitor 150. The sensor 110 has emitters 120 and a detector 130. The emitters 120 typically consist of a red LED (light emitting diode) and an infrared LED that project light through blood vessels and capillaries underneath a tissue site, such as a fingernail bed. The detector 130 is typically a photodiode positioned opposite the LEDs so as to detect the emitted light as it emerges from the tissue site. A pulse oximetry sensor is described in U.S. Patent 6,088,607 entitled "Low Noise Optical Probe," which is assigned to Masimo Corporation, Irvine, CA and incorporated by reference herein.

[0004]   Also shown in FIG. 1, the monitor 150 has drivers 152, a sensor front-end 154, a signal processor 155, a display driver 157, a display 158 and a controller 159. The drivers 152 alternately activate the emitters 120 as determined by the controller 159. The front-end 154 conditions and digitizes the resulting current generated by the detector 130, which is proportional to the intensity of the detected light. The signal processor 155 inputs the conditioned detector signal and determines oxygen saturation based upon the differential absorption by arterial blood of the two wavelengths projected by the emitters 120.

Specifically, a ratio of detected red and infrared intensities is calculated by the signal processor **155**, and an arterial oxygen saturation value is empirically determined based on the ratio obtained, as described with respect to FIGS. **2-3**, below. The display driver **157** and associated display **158** indicate a patient's oxygen saturation along with pulse rate.

[0005] The Beer-Lambert law provides a simple model that describes a tissue site response to pulse oximetry measurements. The Beer-Lambert law states that the concentration c_i of an absorbent in solution can be determined by the intensity of light transmitted through the solution, knowing the pathlength d_λ, the intensity of the incident light $I_{o,\lambda}$, and the extinction coefficient $\varepsilon_{i,\lambda}$ at a particular wavelength λ. In generalized form, the Beer-Lambert law is expressed as:

$$I_\lambda = I_{o,\lambda} e^{-d_\lambda \cdot \mu_{a,\lambda}} \tag{1}$$

$$\mu_{a,\lambda} = \sum_{i=1}^{n} \varepsilon_{i,\lambda} \cdot c_i \tag{2}$$

where $\mu_{a,\lambda}$ is the bulk absorption coefficient and represents the probability of absorption per unit length. The Beer-Lambert law assumes photon scattering in the solution is negligible. The minimum number of discrete wavelengths that are required to solve EQS. **1-2** are the number of significant absorbers that are present in the solution.

[0006] FIG. **2** illustrates top-level computation functions for the signal processor **155** (FIG. **1**), described above. For pulse oximetry, it is assumed that wavelengths are chosen such that there are only two significant absorbers, which are oxygenated hemoglobin (HbO$_2$) and deoxygenated hemoglobin (Hb). In particular, pulse oximetry measurements are conventionally made at a red wavelength corresponding to 660 nm and an infrared wavelength corresponding to 940 nm. At these wavelengths, deoxygenated hemoglobin absorbs more red light than oxygenated hemoglobin, and, conversely, oxygenated hemoglobin absorbs more infrared light than deoxygenated hemoglobin.

[0007] In addition to the differential absorption of hemoglobin derivatives, pulse oximetry relies on the pulsatile nature of arterial blood to differentiate hemoglobin absorption from absorption of other constituents in the surrounding tissues. Light absorption between systole and diastole varies due to the blood volume change from the inflow and outflow of arterial blood at a peripheral tissue site. This tissue site also comprises skin, muscle, bone,

venous blood, fat, pigment, etc., each of which absorbs light. It is assumed that the background absorption due to these surrounding tissues is invariant and can be ignored. That is, the sensor signal generated by the pulse-added arterial blood is isolated from the signal generated by other layers including tissue, venous blood and baseline arterial blood.

[0008]   As shown in FIG. 2, to isolate the pulsatile arterial blood, the signal processor 155 (FIG. 1) computes ratios 215, 265 of the AC portions 212, 262 of the detected red (RD) 201 and infrared (IR) 206 signals with respect to the DC portions 214, 264 of the detected signals 201, 206. Computations of these AC/DC ratios 215, 265 provide relative absorption measures that compensate for variations in both incident light intensity and background absorption and, hence, are responsive only to the hemoglobin in the arterial blood. Further, a ratio of the normalized absorption at the red wavelength over the normalized absorption at the infrared wavelength is computed:

$$RD/IR = (Red_{AC}/Red_{DC})/(IR_{AC}/IR_{DC}) \qquad (3)$$

[0009]   The desired oxygen saturation (SpO$_2$) 282 is then computed empirically from this "red-over-infrared, ratio-of-ratios" (RD/IR) 272. That is, the RD/IR output 272 is input to a look-up table 280 containing empirical data 290 relating RD/IR to SpO$_2$, as described with respect to FIG. 3, below.

[0010]   FIG. 3 shows a graph 300 depicting the relationship between RD/IR and SpO$_2$. This relationship can be approximated from Beer-Lambert's Law, described above. However, it is most accurately determined by statistical regression of experimental measurements obtained from human volunteers and calibrated measurements of oxygen saturation. The result can be depicted as a curve 310, with measured values of RD/IR shown on a x-axis 302 and corresponding saturation values shown on an y-axis 301. In a pulse oximeter device, this empirical relationship can be stored in a read-only memory (ROM) for use as a look-up table 280 (FIG. 2) so that SpO$_2$ can be directly read-out from an input RD/IR measurement. For example, an RD/IR value of 1.0 corresponding to a point 312 on the calibration curve 310 indicates a resulting SpO$_2$ value of approximately 85%.

SUMMARY OF THE INVENTION

[0011]   Saturation measurements from a conventional pulse oximeter depend on a predictable, empirical correlation between RD/IR and SpO$_2$. Tissue optical properties, i.e.

RD absorbance as compared with IR absorbance, however, vary with other patient dependent parameters such as site temperature, pH and total hematocrit (Hct), to name a few, that are not accounted for in the conventional photon absorbance model. A compensated pulse oximeter advantageously utilizes measurements of one or more parameters that are missing from a conventional pulse oximeter to derive a more accurate SpO_2 measurement. Parameter measurements may be derived from multiple parameter sensors, from additional sensors and/or instruments and from manual inputs. A compensated pulse oximeter accounts for these parameters by calibration curve selection, modification or derivation, by measurement output corrections and by dynamic sensor wavelength modification.

BRIEF DESCRIPTION OF THE DRAWINGS

[0012]   FIG. 1 is a block diagram of a prior art pulse oximeter;

[0013]   FIG. 2 is a top-level functional diagram of conventional pulse oximetry signal processing;

[0014]   FIG. 3 is an exemplar graph of a conventional calibration curve;

[0015]   FIG. 4 is a top-level block diagram of a parameter compensated pulse oximeter portion having sensor, external instrument and manual parameter inputs;

[0016]   FIG. 5 is a detailed block diagram of a pulse oximeter having manual parameter inputs;

[0017]   FIG. 6 is a detailed block diagram of a pulse oximeter having a multi-wavelength and site temperature sensor in addition to an external pH monitor input;

[0018]   FIG. 7 is a functional block diagram of parameter compensated signal processing incorporating one embodiment of calibration curve determination;

[0019]   FIG. 8 is a functional block diagram of parameter compensated signal processing incorporating another embodiment of calibration curve determination;

[0020]   FIG. 9 is a functional block diagram of parameter compensated signal processing incorporating measurement output correction; and

[0021]   FIG. 10 is functional block diagram of parameter compensated signal processing incorporating sensor wavelength modification.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Overview

[0022]   Parameter compensated pulse oximetry is described below with respect to monitor interface architectures (FIGS. 4-6) and monitor signal processing functions (FIGS. 7-10). FIG. 4 illustrates a general interface architecture including a primary sensor input for deriving SpO_2 and parameter inputs from sensors, external instruments and manual entry for deriving a more accurate SpO_2. FIG. 5 illustrates a two-wavelength sensor along with manual parameter inputs. FIG. 6 illustrates a multiple wavelength sensor for a derived parameter input, a sensor temperature element for a site temperature parameter input, and an external instrument parameter input.

[0023]   FIGS. 7-8 illustrate a compensated SpO_2 computed from RD/IR utilizing a parameter determined calibration curve. FIG. 9 illustrates a compensated SpO_2 computed from parameter dependent correction of an uncompensated SpO_2. FIG. 10 illustrates a compensated SpO_2 resulting from parameter dependent sensor wavelength modification.

[0024]   The interface architectures according to FIGS. 4-6 may each support signal processing functions according to FIGS. 7-10. As just one of many examples and embodiments, a pulse oximeter has a manual input compensation parameter, such as described with respect to FIG. 5. The manual input may be, say, a blood gas derived parameter, such as HbCO or MetHb to name just a few. This parameter is utilized to select, modify, derive or otherwise determine a calibration curve so as to compute a more accurate measure of SpO_2.

Parameter Compensation Architecture

[0025]   FIG. 4 illustrates a parameter compensated pulse oximeter 400 having a sensor interface 410, an external instrument interface 420 and a user interface 430. The sensor interface 410 connects to one or more tissue site sensors 10, which may be optical or non-optical devices configured to provide invasive or noninvasive measurements of tissue site properties. The sensor interface 410 has a primary input 412 and one or more sensor parameter inputs 414. The primary input 412 is adapted to provide tissue site properties via sensor elements. A sensor parameter input 414 is also adapted to provide tissue site related

properties, which include optical or nonoptical properties. In one embodiment, the primary input 412 is a detector response to at least two emitter wavelengths after transmission through or reflection from a tissue site, from which the pulse oximeter may derive at least a conventional measure of oxygen saturation, as described with respect to FIGS. 1-3 above. An example of this embodiment is described with respect to FIG. 5, below. In another embodiment, the sensor 10 utilizes more than two wavelengths so that the pulse oximeter 400 may derive the concentrations of other blood constituents in addition to oxygen saturation, such as total hematocrit (Hct), carboxyhemoglobin (HbCO) and methemoglobin (MetHb), to name a few. An example of this is described with respect to FIG. 6, below. The same sensor or a different sensor provides a measure of tissue site temperature on a sensor parameter input 414, such as described with respect to FIG. 6, below.

[0026] Also shown in FIG. 4, an external instrument interface 620 connects to one or more external instruments 20, which may monitor optical or non-optical properties, invasively or noninvasively, from the sensor tissue site or from other portions of a patient or a patient's immediate environment. In one embodiment, the external instrument 20 is a pH monitor, as described with respect to FIG. 6, below.

[0027] Further shown in FIG. 4, a user interface 430 accepts one or more manual input parameters 432. As an example, the user interface 430 may be a keyboard input operating in conjunction with a user display, which may range from a small character display to a CRT providing a computer-generated graphical user interface (GUI). The manual inputs may be any information related to a patient or a patient's immediate environment. In one embodiment, a manual input of blood gas measurements, such as are obtainable from a CO-oximeter, is provided. Blood gas measurements may include arterial oxygen saturation (SaO$_2$), Hct, HbCO, MetHb to name a few.

[0028] Additionally shown in FIG. 4, the sensor interface 410, external instrument interface 420 and user interface 430 each provide inputs to the signal processor 440. The signal processor utilizes the primary input 412 and one or more parameter inputs 403 to generate a compensated output 442. In one embodiment, the output 442 is an SpO$_2$ measurement that is derived from both the primary input 412 and the parameter inputs 403.

[0029]   FIG. 5 illustrates one embodiment of a parameter compensated pulse oximeter **500** having a sensor **510** and manual inputs to a monitor **560**. In particular, drivers **562** activate emitters **520** that project two wavelengths into a tissue site, and a detector **540** responsive to the emitters **520** provides a primary input **542** to a sensor front-end **564**, as described above. A user interface **565** accepts manual inputs such as temperature (T), pH, Hct, HbCO and MetHb to name a few, the values of which a user may obtain from separate instruments. The sensor front-end **564** and user interface **565** output to the signal processor **566** a detector signal along with the manually input parameters. The signal processor **566** computes a compensated SpO_2 measurement from the detector signal and these parameters, as described with respect to FIGS. **7-10**, below. The compensated SpO_2 measurement is then displayed **567, 568** in a manner similar to that described above with respect to FIG. **1**.

[0030]   FIG. 6 illustrates another embodiment of a parameter compensated pulse oximeter **600** having a sensor **610** and an external pH monitor **650** providing inputs to a pulse oximetry monitor **660**. The sensor **610** has multiple wavelength emitters **620** and a site temperature element **630**. Multiple wavelengths may be achieved, for example, by utilizing multiple LEDs each manufactured for a specific wavelength according to the number of wavelengths desired. Alternatively, one or more LEDs having drive current dependent wavelengths may be utilized, where the drive current is controlled to shift between multiple wavelengths. The site temperature element **630** provides a site temperature parameter input to the sensor front-end **664**. In one embodiment, the site temperature element **630** is a thermistor located on the sensor **610** proximate the emitters **620** or proximate the detector **640**. The detector **640** provides a multiple wavelength signal output that is combined with a site temperature output to a sensor front-end **664**. An instrument interface **665** is adapted to input pH readings from the pH monitor **650**. The sensor drivers **662** provide multiplexed activation of the multiple emitters **620** as determined by the controller **669**. The signal processor **666** accepts outputs from the sensor front-end **664** and the instrument interface **665**. In addition, the signal processor **666** computes an SpO_2 measurement from the detector signal along with other blood constituents, utilizing the multiple wavelength signal from the detector **640**. Further, the signal processor **666** derives a compensated SpO_2 measurement

from the input parameters, as described with respect to FIGS. **7-10**, below. The compensated SpO₂ measurement is then displayed **667, 668** in a manner similar to that described above.

[0031] As shown in FIG. **6**, a pulse oximetry sensor **610** may be improved for use in conjunction with a parameter compensated pulse oximeter by increasing the number of wavelengths projected by the emitters **620**, which allows the resolution of more than two blood constituents, as described above. Further, the sensor **610** may be improved by adding the capability to measure various parameters, such as site temperature. Alternatively, as shown in FIG. **5**, pulse oximeter performance can be improved at reduced costs by utilizing simple sensors in conjunction with other instrumentation and/or manual inputs to provide additional input parameters.

[0032] The sensor **610** may also have an information element (not shown) that describes information regarding the sensor. In one embodiment, the information element provides the monitor **660** with information regarding available wavelengths for the emitters **620** and/or information regarding the temperature element **630**, such as the resistance-temperature characteristics of a thermistor. An information element is described in U.S. Patent No. 6,011,986 entitled " Manual And Automatic Probe Calibration," assigned to Masimo Corporation, Irvine, CA and incorporated by referenced herein.

Parameter Compensation Signal Processing

[0033] FIG. **7** illustrates a calibration curve determination function **700** having a first look-up table **710**, an associated calibration curve or curves **720**, a second look-up table **730** and a calibration curve determination data set **740**. The calibration curve determination function **700** advantageously selects, modifies, derives or otherwise determines a calibration curve **720** so as to generate a compensated SpO₂ output **718**. The first look-up table **710** has an RD/IR input **712** and generates a SpO₂ output **718** utilizing a calibration curve **720**, such as described with respect to FIGS. **2-3**, above. The second look-up table **730** has one or more compensation parameter inputs **732**, such as temperature, pH, Hct, HbCO and MetHb to name a few, and provides a calibration curve control output **738** according to calibration curve determination data **740**. The control output **738** determines the calibration curve **720** utilized by the first look-up table **710**, according to the compensation parameters **732**. In one

embodiment, the control output **738** selects one of a family of calibration curves **720**. In another embodiment, the control output **738** determines the direction and amount of shift in a calibration curve **720** or a selected one of a family of calibration curves **720**. In yet another embodiment, the control output **738** modifies a calibration curve or a selected one of a family of calibration curves **720**, such as by rotating a calibration curve around a selected point on the curve. In an additional embodiment, the control output **738** specifies one or more points from which a calibration curve **720** is derived. The calibration curves **720** and calibration curve determination data **740** define a relationship between the primary input **712**, the parameter inputs **732** and the compensated output **718**. The calibration curve or curves **720** and associated curve determination data **740** may be determined by statistical regression of experimental measurements obtained from human volunteers and calibrated measurements of oxygen saturation and associated parameters. All or part of the first look-up table **710**, calibration curves **720**, second look-up table **730** and calibration curve determination data set **740** may be replaced by or combined with a mathematical formula or algorithm, theoretically or experimentally derived, that derives a calibration curve or curves or directly computes an SpO_2 output from RD/IR and parameter inputs.

[0034]   FIG. 8 illustrates a calibration curve determination function **800** having a first look-up table **810**, a calibration curve or curves **820**, a second look-up table **830** and associated calibration curve modification data **840**. The calibration curve determination function **800** functions as described with respect to FIG. 7, but has, as input to the second look-up table **830**, the compensated SpO_2 output **818**. In particular, the first look-up table **810** has an RD/IR input **812** and generates a SpO_2 output **818** utilizing a calibration curve **820**. The second look-up table **830** has one or more compensation parameter inputs **832** and has, as an input, the SpO_2 output **818**. The second look-up table **830** provides a calibration curve control output **838** according to calibration curve determination data **840**. The control output **838** determines the calibration curve **820** utilized by the first look-up table **810**, according to the compensation parameters **832** and the SpO_2 output **818**. As described above with respect to FIG. 7, the control output **838** may select one of a family of calibration curves **820**, may determine the direction and amount of shift in a calibration curve **820** or a selected one of a family of calibration curves **820**, may modify a calibration curve or a selected one of

a family of calibration curves **820**, such as by rotating a calibration curve around a selected point on the curve, or may specify one or more points from which a calibration curve **820** is derived or may cause a combination of these actions. The calibration curve or curves **820** and associated curve determination data **840** may be determined by statistical regression of experimental measurements obtained from human volunteers and calibrated measurements of oxygen saturation and associated parameters.

[0035]   In one advantageous embodiment, there is a single parameter input **832** comprising one or more blood gas measurements of SaO_2. According to these SaO_2 measurements, a calibration curve **820** is selected, modified, such as by shifting or rotating a calibration curve, or otherwise derived so that subsequently derived SpO_2 measurements are consistent with blood gas measurements. In a particular embodiment, so as to reduce sensitivity, multiple blood gas input values are taken over a range of saturation values and are evaluated for consistency within a tolerance range before the current calibration curve is replaced or modified.

[0036]   FIG. 9 illustrates a parameter compensation function **900** for an uncompensated SpO_2 measurement having a first look-up table **910**, a calibration curve or curves **920**, a second look-up table **930** and associated correction data **940**. The parameter compensation function **900** differs from the calibration determination function **700** (FIG. 7) described above in that, as shown in FIG. 9, an uncompensated SpO_2 value **918** is calculated and corrected to yield a compensated SpO_2' value **938**. This contrasts with a compensated SpO_2 value being directly derived from RD/IR, as described with respect to FIG. 7, above. In one embodiment, the parameter compensation function **900** advantageously upgrades the results of a conventional pulse oximeter. The first look-up table **910** and calibration curve **920** may be as described with respect to FIGS. 2-3, above. The second look-up table **930** and associated correction data **940** may be as described with respect to FIG. 7, above, except that an uncompensated value of SpO_2 **918** is an input to the look-up table **930** rather than RD/IR **912**. As above, the correction data set **940** may be determined by statistical regression of experimental measurements obtained from human volunteers and calibrated measurements of oxygen saturation and associated parameters or may be replaced by or combined with a

mathematical formula or algorithm that directly computes a compensated SpO_2 output from uncompensated SpO_2 and parameter inputs.

[0037]   In one advantageous embodiment, a blood gas measurement of HbCO and/or MetHb is manually entered into a pulse oximeter and utilized to generate a compensated value of SpO_2. As described above, conventional pulse oximetry utilizes two wavelengths, assuming that Hb and HbO_2 are the only significant absorbers. However, carboxyhemoglobin (HbCO) and methemoglobin (MetHb) may also be significant absorbers at RD and IR wavelengths. The presence of significant concentrations of HbCO and MetHb have different effects on a conventional pulse oximeter estimate of oxygen saturation. HbO_2 and HbCO have similar extinctions at the RD wavelength, as do MetHb and Hb. At the IR wavelength, HbCO is relatively transparent whereas MetHb has greater extinction than the other hemoglobins. The two wavelength assumption has the effect of lumping HbO_2 and HbCO together, i.e. HbCO is counted as an oxygen carrying form of hemoglobin, causing a conventional pulse oximeter to overestimate oxygen saturation. As MetHb increases, RD/IR tends to unity and SpO_2 to a constant (e.g. 85%) regardless of oxygen saturation. A manually entered value of HbCO and or MetHb is used as a parameter in conjunction with the functions described above with respect to any of FIGS. 7-9, so as to distinguish these hemoglobin species from HbO_2 and Hb, providing a more accurate, HbCO and/or MetHb compensated, value of SpO_2.

[0038]   FIG. 10 illustrates a wavelength modification function 1000 having a first look-up table 1010, a calibration curve or curves 1020, a second look-up table 1030 and associated wavelength modification data 1040. The wavelength modification function 1000 advantageously changes sensor wavelength to generate a compensated SpO_2 output 1018. The first look-up table 1010 has an RD/IR input 1012 and generates an SpO_2 output 1018 utilizing conventional calibration curves 1020. The wavelength control output 1038 provides a calibration curve input for selecting a wavelength dependent calibration curve 1020. The second look-up table 1030 has SpO_2 1018 and parameter 1032 inputs and provides a sensor wavelength control output 1038 according to associated wavelength modification data 1040. As above, the look-up tables may be replaced by or combined with mathematical formulas or algorithms. The wavelength control output 1038 is a feedback path to a controller 669 (FIG.

6) and/or drivers **662** (FIG. **6**). In one advantageous embodiment, there are no parameter inputs **1032**, and the wavelength control output **1038** is dependent on SpO_2. In this manner, sensor wavelength can be dynamically adjusted based upon saturation levels, e.g. a first red and/or IR wavelength may be used in low saturation conditions and a second red and/or IR wavelength may be used in normal saturation conditions.

[0039]   A parameter compensated pulse oximeter has been disclosed in detail in connection with various embodiments. These embodiments are disclosed by way of examples only and are not to limit the scope of the claims that follow. One of ordinary skill in the art will appreciate many variations and modifications.